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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,557	05/02/2002	Audrey Goddard	GNE.3230R1C39	9770

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EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/063,557	GODDARD ET AL.	
	Examiner	Art Unit	
	David J. Blanchard	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/2/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02 October 2006 has been entered.

2. Claim 6 is cancelled.

3. Claims 1-5 are pending and under examination.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

5. The IDS submitted 02 October 2006 have been fully considered. A signed copy of the IDS accompanies this Office Action.

Objections/Rejections Withdrawn

6. The objection to the title as not being descriptive of the claimed invention is withdrawn in view of the newly submitted title filed 10/2/2006.

7. The rejection of claims 1-5 under 35 U.S.C 101 because the claimed invention is not supported by a substantial asserted utility or a well-established utility is withdrawn for the following reasons:

The claims of the instant invention are directed to an isolated antibody that specifically binds to the polypeptide of SEQ ID NO:50. The specification provides several asserted utilities, including that the PRO polypeptides of the present invention may be differentially expressed in a diseased tissue as compared to a normal tissue of the same tissue type.

Applicant states at page 8 of their response that the gene expression data in the specification, Example 18, shows that the mRNA associated with the PRO1069 polypeptide (SEQ ID NO:49) was more highly expressed in normal kidney compared to kidney tumor. Gene expression was analyzed using standard semi-quantitative PCR amplification reactions of cDNA libraries isolated from different human tumor and normal human tissue samples. Identification of the differential expression of the PRO1069 polypeptide-encoding gene in tumor tissue compared to the corresponding normal tissue renders the molecule useful and enabled as a diagnostic tool for the determination of the presence or absence of tumor.

Example 18 at page 140 of the instant specification demonstrates differential expression of PRO1069 cDNA using quantitative PCR amplification reactions. DNA59211-1450 was shown to be more highly expressed in normal kidney compared to kidney tumor, in this Example. Applicant states at page 9 of the response that Example 18 utilizes a more accurate and reliable method of assessing changes in mRNA levels, namely quantitative PCR analysis (RT-PCR). Applicant relies on more than 140 references (see IDS filed 4/11/2006), where expression levels of mRNA, measured by quantitative PCR, were found to have a good correlation to the expressed protein levels.

It had been previously argued in the previous Office actions that mRNA levels were not predictive of protein levels, citing references by Alberts [a], Alberts [b], Lewin, Zhigang, Meric, Haynes et al, Gygi et al, Greenbaum, Jang, Lian et al, Fessler., Hanash [a] and Hanash [b], Winstead and Irving. However, these references were measuring and analyzing mRNA levels using microrarrays, not using quantitative PCR analysis and the art recognizes that the results obtained by microarray are not always the same as the results obtained using quantitative PCR (for example, see Oda et al. Virchows Arch. 430:99-105, 1997, specifically page 104, column 1, paragraph 2; cited on IDS filed 10/2/06). While the PTO found several references in which the protein expression levels did not correlate with mRNA levels measured by quantitative PCR (see Sugg et al., Clinical Endocrinology 49: 629-637, 1998, cited on IDS filed 10/2/06; Toler et al., Am. J. Obstet. Gynecol. 194:e27-e31, 2006, cited on IDS filed 10/2/06; Berner et al. Histopathol. 42: 546-554, 2003, cited on IDS filed 10/2/06; Brooks et al. Am. J. Physiol. Renal Physiol. 284: F218-F228, 2003, cited on IDS filed 10/2/06), the majority of the references which were found, including those cited by Applicant, demonstrated a correlation between mRNA levels measured by quantitative PCR and protein expression levels.

Applicant asserts that the expression levels of protein correlate to mRNA (cDNA) levels when the cDNA is measured by quantitative PCR (i.e. RT-PCR). Applicant has provided more than 140 references in support of this position. The prior art of record (Alberts [a], Alberts [b], Lewin, Zhigang, Meric, Haynes et al, Gygi et al, ect), argued by the Examiner, is not specifically directed to message levels measured by RT-PCR.

Based on the totality of evidence of record, one of skill in the art would find it more likely than not that an increase in message as measured by RT-PCR would be predictive of an increase in protein expression levels, absent evidence to the contrary. Therefore, the data presented in Example 18, which demonstrates differential expression of the nucleic acid encoding PRO1069, also supports a conclusion of differential expression of the PRO1069 polypeptide. Therefore, one of ordinary skill in the art would be able to use the PRO1069 polypeptide diagnostically for distinguishing melanoma from normal skin, as asserted by Applicant.

8. The rejection of claims 1-5 under 35 U.S.C. 112, first paragraph, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention is withdrawn for the reasons set forth above (see item no. 7).

Response to Arguments

Priority

Applicant has amended the priority and no longer claims priority to claims priority to USSN 09/380,137, PCT/US99/12252 and 60/088,740. Priority is granted to PCT/US00/23328, filed 24 August 2000, as the disclosure of '328 is identical to the instant disclosure.

9. The rejection of claims 1-2 and 4-5 are rejected under 35 U.S.C. 102(a) as being anticipated by Lal et al (WO 00/00610, 1/6/2000, cited on PTO-892 mailed 4/15/2004) is maintained.

The response filed 10/2/2006 argues with the previously submitted Declaration under 37 CFR 1.131 by Goddard et al filed 10/14/2005 to establish prior invention of the claimed subject matter prior to Lal's publication date, i.e., 1/6/00 as applied. Applicants' arguments have fully been considered but are not found persuasive. The priority of the instant application has been amended such that the earliest effective filing date is 8/24/2000, which is after the publication date of Lal et al. The Declaration filed on 10/14/2005 under 37 CFR 1.131 has been considered but is ineffective to overcome the applied reference. The evidence submitted is insufficient to establish a conception of the invention or reduction to practice prior to the effective date of the Lal et al reference because the Declaration states that an experiment performed on June 13, 2000, in which primers were used to determine the expression level of DNA59211-1450 (SEQ ID NO:49 encoding the claimed polypeptide SEQ ID NO:50) in various tumor samples. There must be a contemporaneous recognition and appreciation of the invention for there to be conception. Silvestri v. Grant, 496 F.2d 593, 596, 181 USPQ 706, 708 (CCPA 1974). There is insufficient evidence of a recognition or appreciation of the claimed invention or a permanent idea of the complete and operable invention prior to the experiment performed on June 13, 2000. Bosies v. Benedict, 27 F.3d 539, 543, 30 USPQ2d 1862, 1865 (Fed. Cir. 1994). It would have been impossible to envisage the expression level of DNA59211-1450 in normal kidney compared to kidney tumor prior to

the experimental work on June 13, 2000. The first disclosure of the sequences of SEQ ID NO:49 and 50 in US Provisional Application 60/088,740, filed June 10,1998 does not provide a contemporaneous recognition and appreciation of the invention because there is no recognition or appreciation of the differential expression of DNA59211-1450 in normal kidney compared to kidney tumor, upon which applicant relies for utility and enablement, prior to the experimental work on June 13, 2000. Subsequent testing or later recognition may not be used to show that a party had contemporaneous appreciation of the invention. See MPEP 715.07.

For these reasons and those already of record, the rejection is maintained.

10. The rejection of claims 1-2 and 4-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Walker et al (U.S. Patent 6,277,574 B1, 4/9/1999) is maintained.

The response argues as above that the previously submitted Declaration under 37 CFR 1.131 by Goddard et al filed 10/14/2005, which according to applicant establishes conception of the claimed invention prior to April 9, 1999 and diligence in reducing the invention to practice. Applicant concludes that Walker is not available as prior art. Applicants' arguments have fully been considered but are not found persuasive. The priority of the instant application has been amended such that the earliest effective filing date is 8/24/2000, which is after the filing date of Walker et al. The Declaration filed on 10/14/2005 under 37 CFR 1.131 has been considered but is ineffective to overcome the applied reference. The evidence submitted is insufficient to establish a conception of the invention or reduction to practice prior to the effective date

of the Walker et al reference because the Declaration states that an experiment performed on June 13, 2000, in which primers were used to determine the expression level of DNA59211-1450 (SEQ ID NO:49 encoding the claimed polypeptide SEQ ID NO:50) in various tumor samples. There must be a contemporaneous recognition and appreciation of the invention for there to be conception. Silvestri v. Grant, 496 F.2d 593, 596, 181 USPQ 706, 708 (CCPA 1974). There is insufficient evidence of a recognition or appreciation of the claimed invention or a permanent idea of the complete and operable invention prior to the experiment performed on June 13, 2000. Bosies v. Benedict, 27 F.3d 539, 543, 30 USPQ2d 1862, 1865 (Fed. Cir. 1994). It would have been impossible to envisage the expression level of DNA59211-1450 in normal kidney compared to kidney tumor prior to the experimental work on June 13, 2000. The first disclosure of the sequences of SEQ ID NO:49 and 50 in US Provisional Application 60/088,740, filed June 10,1998 does not provide a contemporaneous recognition and appreciation of the invention because there is no recognition or appreciation of the differential expression of DNA59211-1450 in normal kidney compared to kidney tumor, upon which applicant relies for utility and enablement, prior to the experimental work on June 13, 2000. Subsequent testing or later recognition may not be used to show that a party had contemporaneous appreciation of the invention. See MPEP 715.07.

For these reasons and those already of record, the rejection is maintained.

11. The rejection of claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al (U.S. Patent 6,277,574 B1, 4/9/1999) in view of Queen

et al (U.S. Patent 5,530,101, issued 6/96, cited previously on PTO-892 mailed 4/15/2004) is maintained.

Applicant argues as above for Walker, i.e., Applicants have demonstrated conception of the claimed invention prior to April 9, 1999 and diligence in reducing the invention to practice. Applicant concludes that Walker is not available as prior art. Applicants' arguments have fully been considered but are not found persuasive. The examiner's rebuttal above for Walker et al applies here as well and for these reasons the rejection is maintained.

Conclusions

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827